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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/603,832	06/26/2000	Leslie H. Kondejewski	7900-0015.30	2421
26181	7590	05/06/2004	EXAMINER	
FISH & RICHARDSON P.C. 3300 DAIN RAUSCHER PLAZA MINNEAPOLIS, MN 55402			MITRA, RITA	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/603,832	<b>Applicant(s)</b> KONDEJEWSKI ET AL.	
	<b>Examiner</b> Rita Mitra	<b>Art Unit</b> 1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on 17 February 2004.

2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 21-38 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 21-38 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____. 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____.
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### **DETAILED ACTION**

The request filed on February 17, 2004 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/603832 is acceptable and an RCE has been established. An action on the RCE follows.

#### ***Status of the Claims***

Applicants' response to office action dated September 8, 2003, filed on February 17, 2004 is acknowledged. Claims 21 and 30 have been amended and entered. Therefore, claims 21-38 are currently pending to which the following grounds for rejection are or remain applicable.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

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reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 21-24 and 30-33 stand/are rejected under 35 U.S.C. 102(e) as being anticipated by Cooper et al. (US Patent 6,174,528 B1, issue date January 16, 2001, earlier filing date July 31, 1997). The reference teaches chimeric peptides comprising one or more protective epitopes in a conformation enabling immunological interactivity and to vaccine compositions comprising same (see abstract), wherein the chimeric peptide comprises a first amino acid sequence comprising a conformational epitope inserted within a second amino acid sequence, wherein first and second amino acid sequences are derived from peptides polypeptides or proteins having similar native conformation (column 2, lines 26-32), wherein said second amino acid sequence folds to an alpha helical coiled-coil conformation (column 2, lines 45-49). The second amino acid sequence constitutes a "framework peptide," the construction of which is based on a template of the seven amino acid residue repeat: (a-b-c-d-e-f-g)<sub>n</sub>, wherein a and d positions have large apolar residues, positions b, c and f are generally polar and charged and positions e and g generally favor interchain ionic interactions, wherein n= 3 or 4 (see column 3, lines 10-28, Example 11, column 14, line 55 to column 15, line 24. Cooper's polypeptide is the coiled-coil protein, which comprises the formula (abicidefigi)<sub>n</sub>, where i=1,2,...,n (claims 21 and 30); and n is at least three (claims 24 and 33). Cooper also teaches the preparation of the polypeptide by selecting inherently a solvent accessible region of an epitope of a selected natural protein, wherein the region is not in a coiled-coil conformation in its native state, and inserting the amino acids from the said region into the bi, ci, ei, fi, and gi positions wherein the (abicidefigi)<sub>n</sub> forms a coiled-coil (column 5, line 61 to column 6, line 23 and Example 11, column 14, line 55 to column 15, line 24 and Example 18, column 18, line 50 to column 19, line 13). This inference is borne out of the fact that "b, c, f, positions are generally polar and charged" as taught by Cooper et al. (column 18, lines 58-60). It is well known to an ordinary practitioner that polar and charged moieties of a chemical compound are accessible to solvents, whereas apolar residues (e.g., a and d positions of the polypeptide) are not accessible to solvents. Further the reference teaches independently inserting an amino acid selected from within the sequence:

LRRDLASREAKKQVEKALE (column 5, line 61 to column 6, line 23), this step is considered

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to disclose claim 21b and claim 30, which recite: selected from the group consisting of leucine, isoleucine, valine, phenylalanine, methionine, tyrosine, and derivatives thereof, into each of the a and d positions. Thus anticipating claims 21 and 30.

Moreover, it has been explicitly taught and suggested by Cooper et al, "it has also been noted that when positions a and d are occupied by V and L, or I and L, a coiled coil dimer is favoured whereas I and I favor trimer formation, and L and I favor tetramer interactions (Example 11, column 14, lines 65 to column 15, lines 1-2; Example 18, column 18, lines 60-64)"

Cooper et al. teach the polypeptide, wherein a is isoleucine, and d is leucine (Example 11, column 14, line 65 to column 15, line 23 and Example 18, column 18, lines 60-64), thus anticipating claims 22 and 31 of instant application.

Cooper et al. teach the polypeptide, wherein the coiled-coil polypeptide is comprised of two polypeptide chains arranged in a parallel configuration (Example 18, column 18, lines 53-57), thus anticipating claims 23 and 32. Therefore, claims 21-24 and 30-33 of the instant application are being anticipated by Cooper et al.

Claims 21, 26, 28 and 30, 35, 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Fishleigh et al. (US Patent 5,773,572, issue date June 30, 1998, filed June 2, 1997). The reference teaches Prion Protein fragments, wherein the polypeptides having at least one antigenic site of a prion protein (see abstract). The polypeptide has 85.2% sequence identity to SEQ ID NO: 6 (see alignment result 1, Fishleigh et al., Database: Issued\_Patents\_AA, Accession NO: US-08-244-701B-36, June 2, 1994). Fishleigh's polypeptide is considered for the residues of an epitope having a sequence of SEQ ID NO: 6 of the instant application, thus anticipating claims 21, 26, 28 and 30, 35, 37.

Claims 21, 26, 28 and 30, 35, 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Prusiner et al. (US Patent 5,962,669, issue date October 5, 1999, filed June 2, 1997). The reference teaches a Prion Protein Modulator Factor (PPMF), which is an auxiliary factor in prion replication. PPMF is primarily characterized by its ability to bind to PrPc and facilitate a conformational change from PrPc to PrPsc. More specifically the teaching relates to a

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discontinuous epitope of PrP protein, wherein the PPMF binds to that epitope (abstract and column 1, lines 12-18). The PrP protein epitope has 100% sequence identity to SEQ ID NO: 5 (see alignment result 6, Prusiner et al., Database: Issued\_Patents\_AA, Accession NO: US-08-868-162A-21, June 3, 1997), and 100% sequence identity to SEQ ID NO: 7 (see alignment result 6, Prusiner et al., Database: Issued\_Patents\_AA, Accession NO: US-08-868-162A-21, June 3, 1997). Prusiner's epitope is considered for the residues of an epitope having a sequence of SEQ ID NO: 5 and SEQ ID NO: 7 of the instant application, thus anticipating claims 21, 26, 28 and 30, 35, 37.

Claims 25, 27, 29, 34, 36 and 38 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

No claim is allowed.

### ***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (571) 272-0954. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached at (571) 272-0951. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is

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(703) 872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0547.

Rita Mitra, Ph.D.

May 1, 2004

  
CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
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